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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,043	01/09/2008	**Volker Sandig**	22112.0002U1	5415

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EXAMINER	
LEAVITT, MARIA GOMEZ	
ART UNIT	PAPER NUMBER
1633	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,043	SANDIG ET AL.	
	Examiner	Art Unit	
	MARIA LEAVITT	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05-01-2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-13* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is 371 filing of PCT/EP04/52789, filed 11/03/2004, which claims benefit to EPO 03025158.1, filed 11/03/2003.

The amendment filed 05/01/2006 has been received and entered. Claims 1-13 have been entered.

Claim Interpretation: Claim 10 is directed to "uses". The claim is indefinite since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. Additionally, because these claims to set forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim. For the sake of compact prosecution, the Examiner has interpreted claim 10 be a method of using **an avian cell line immortalized** comprising a combination of viral and/or cellular genes in production of biological or viruses. If Applicants do not wish for these claims to be interpreted as methods of using **an avian cell line immortalized**, Applicants are invited to amend the claims, at which point, the Examiner will determine if the amended claims fall within the elected group.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. **Claims 1-7** are drawn to **an avian cell line** immortalized with a combination of viral and/or cellular genes, at least one first gene affecting the function of the retinoblastoma protein and at least one second gene affecting the p53 protein or a family member.

II. **Claim 8-9** are drawn to a **method for preparing an avian cell line** immortalized with a combination of viral and/or cellular genes comprising transforming/transfecting a starting cell with the first and second gene.

III. **Claims 10-12** are drawn to **a method of producing viruses** which comprises (i) contacting said viruses with an avian cell line immortalized with a combination of viral and/or cellular genes and (ii) cultivating said viruses on said cell line.

IV. **Claims 10 and 13** are drawn to a **method for producing recombinant proteins** which comprises (i) introducing a gene coding for a recombinant protein, operably linked to a promoter, into an avian cell line immortalized with a combination of viral and/or cellular genes, (ii) cultivating said modified cell line and (iii) harvesting the recombinant protein.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons:

37 CFR 1.475 (c) states:

> "If an application contains to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present"

37 CFR 1.475 (d) also states:

"If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c)".

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons: the technical feature linking Groups I-IV appears to be that they all relate to immortalized avian cell lines transformed with at least two viral or cellular genes, one of which causes cell cycle progression whereas the other interferes with innate protective mechanisms of the cell induced by deregulated replication, and methods suitable for production of biologicals or viruses for vaccination. However, prior art has exemplified by Kim et al., et al (HANTS, GB, vol. 20, no. 21,2001, pages 2671-2682, XP001157349 ISSN: 0950-9232, of record) described the creation of immortalized chicken embryo fibroblast cell lines which have been established in continuous cell culture wherein the expression pattern of p53 and 2F-1 has been tested, showing a down and up-regulation, respectively. Therefore, the technical feature linking the invention of groups I-IV does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over prior art for the reasons set forth above.

The inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Inventions of Groups I-IV are drawn to materially different and distinct inventive concepts, having different chemical structures, physical properties and biological functions. For example, inventions of Group IV requires the step of (i) introducing a gene coding for a

recombinant protein which active step is not disclosed as required by the inventions of Group II or III. Likewise, inventions of Group III require contacting viruses with an avian cell line immortalized and cultivating said viruses on said cell line which active steps are not required by the invetions of Groups II or IV. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I-IV do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features for the reasons set forth above.

MPEP 1893.03(d) states:

> If an examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable (i.e., meet the requirements of 35 U.S.C. 101, 102, 103 and 112), the nonelected invention(s) should be considered for rejoinder. Any nonelected product claim that requires all the limitations of an allowable product claim, and any nonelected process claim that requires all the limitations of an allowable process claim, should be rejoined. See MPEP § 821.04 and § 821.04(a). Any nonelected processes of making and/or using an allowable product should be considered for rejoinder following the practice set forth in MPEP §

In addition, **if Groups** I **is elected in relation to the combination of a E1A (first gene) and E1B (second gene)**, a **further restriction** is required among the sequences of the **E1A gene** :bp 1193 to 2309 of SEQ ID NO:7 and the sequence complementary to bp 4230 to 3113 of SEQ ID NO:9, **the E1B:** bp 1145 to 3007 of SEQ ID NO:8 or the sequence complementary to bp 2345 to 550 of SEQ ID NO:9.

If Groups I **is elected in relation to the combination of a orf22 (first gene) and GAM-1(second gene)**, a **further restriction** is required among the sequences the sequence represented

by the sequence complementary to bp 1252 to 635 of SEQ ID NO:10, and the sequence complementary to bp 3138 to 2290 of SEQ ID NO:10.

The inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As the technical feature of a nucleotide sequence coding for a polypeptide, linking the members does not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the each nucleic acid does not overlap in scope with the others, are not obvious variants, and have materially different functions, the requirement for unity of invention is not fulfilled. **Applicants must elect one specific polypeptide SEQ ID NO. Of note, this is not a species election but a Group restriction.**

Species restriction

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Should Group I be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

1) a viral gene or a cellular gene as recited in claim 1.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each of the species results in **a unique** avian cell

line immortalized with genes exhibiting unique chemical properties with unique uses and limitations that do not extend one to the other.

Applicant is required, in reply to this action, to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1 and 10 are generic.

If a **viral gene** is elected, a further species election is required **for the first gene** and **for the second gene,** or the first and second gene combinations from the following group:

2) (first gene) an adenovirus E1A gene from mastadenoviruses, , an E7 gene of papillomaviruses, an orf 22 gene of avian adenoviruses, E43 open reading frames from ovine attadenovirus, as recited in claim 3.

3) (second gene) Adenovirus E1 B55K protein of all groups, GAM-1 of CELO, the E6 protein of papillomaviruses, as recited in claim 3.

4) the E1 A (first gene) and E1 B (second gene) region; the genes orf22 (first gene) and GAM-1 (second gene), as recited in claim 4.

If a **cellular gene** is elected, a further species election is required **for the first gene** and from the following group:

5) Cyclins D1, D2 or D3, a mutated CDK4 not susceptible to inactivation by p161NK4a, as recited in claim 3.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each of the species results in **a unique** avian cell line immortalized with genes exhibiting unique chemical properties with unique uses and limitations that do not extend one to the other.

Applicant is required, in reply to this action, to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1 and 10 are generic.

6) Chicken, duck, goose or quail, as recited in claim 3.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each of the species results in **a cell line** immortalized with genes exhibiting unique chemical properties with unique uses and limitations that do not extend one to the other.

Applicant is required, in reply to this action, to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1 and 10 are generic.

7) Fibroblasts, cells from isolated body segments (somites) or separated individual organs including neuronal, brain, retina, kidney, liver, heart, muscle and extraembryonic tissues and membranes protecting the embryo, as recited in claim 3.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each of the species results in **a unique primary cell line** immortalized with genes exhibiting unique chemical properties with unique uses and limitations that do not extend one to the other.

Applicant is required, in reply to this action, to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1 and 10 are generic.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maria Leavitt/

Maria Leavitt
Primary Examiner, Art Unit 1633